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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/802,644	03/17/2004	Linda D. Martin	5051-574CT	3963

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EXAMINER	
HADDAD, MAHER M	
ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 08/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/802,644	MARTIN ET AL.	
	Examiner	Art Unit	
	Maher M. Haddad	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-51 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-51 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. Examiner considers claim 48 was intended to depend from claim 47.

2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 4, 8-11, 16, 20-23, 25-27, 32-34, 38, 39, 41-42, and 48-51, drawn to a method of regulating an inflammation or cellular secretory process (granule release) in a subject comprising administering a composition comprising a MANS peptide or an active fragment thereof, wherein inflammation is respiratory diseases, classified in Class 514, subclass 2.

II. Claims 5, 8-11, 17, 20-23, 25-27, 32-34, 38, 39 and 48-51, drawn to a method of regulating an inflammation or cellular secretory process (granule release) in a subject comprising administering a composition comprising a MANS peptide or an active fragment thereof, wherein inflammation is bowel diseases, classified in Class 514, subclass 2.

III. Claims 6, 8-11, 18, 20-23, 25-27, 32-34, 38-39 and 48-51, drawn to a method of regulating an inflammation or cellular secretory process (granule release) in a subject comprising administering a composition comprising a MANS peptide or an active fragment thereof, wherein inflammation is skin diseases, classified in Class 514, subclass 2.

IV. Claims 7, 8-11, 19-23, 25-27, 32-34, 38-39 and 48-51, drawn to a method of regulating an inflammation or cellular secretory process (granule release) in a subject comprising administering a composition comprising a MANS peptide or an active fragment thereof, wherein inflammation is arthritis, classified in Class 514, subclass 2.

V. Claims 7, 8-11, 19-23, 25-27, 32-34, 38-39 and 48-51, drawn to a method of regulating an inflammation or cellular secretory process (granule release) in a subject comprising administering a composition comprising a MANS peptide or an active fragment thereof, wherein inflammation is cystic fibrosis, classified in Class 514, subclass 2.

VI. Claims 28-30, 35-36 and 44-46, drawn to a method of reducing inflammation/mucus secretion in a subject comprising administering a compound wherein the compound is an antisense oligonucleotide directed against the coding sequence of a MARCKS protein or an active fragment thereof, classified in Class 514, subclass 44.

Claims 1-3, 12-15, 24, 31, 37 and 40 are linking claims and will be examine along with elected Group I.

Claims 1-3, 12-15, 24, 31, 37 and 47 are linking claims and will be examine along with any one of elected Group II-V.

Claims 24, 31 and 43 are linking claims and will be examine along with elected Group VI.

3. Groups I-VI are different methods. A method of reducing and a method of regulating inflammation or cellular secretory process, wherein inflammation is respiratory diseases, bowel diseases, skin diseases, arthritis or cystic fibrosis differ with respect to ingredients, method steps, and endpoints; therefore, each method is patentably distinct.

4. These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by different classification and/or recognized divergent subject matter. Further, even though in some cases the classification is shared, a different field of search would be required based upon the structurally distinct products recited and the various methods of use comprising distinct method steps. Therefore restriction for examination purposes as indicated is proper.

Species Election

5. Irrespective of whichever group applicant may elect, applicant is further required under 35 US 121 (1) to elect a single disclosed species to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

A. If Group I is elected, applicant is further required to elect a method of regulating an inflammation or cellular secretory process (granule release) in a subject comprising administering a composition comprising a MANS peptide or an active fragment thereof, wherein inflammation is respiratory diseases, wherein the respiratory disease is a) asthma, b) chronic bronchitis or c) COPD. These species are distinct because the pathological conditions differ in etiologies and therapeutic endpoints; thus each condition represents patentably distinct subject matter. Applicant is further required to elect an inflammatory mediator such as a) neutorphils, b) basophils, c) eosinophils, d) monocytes or e) leukocytes. These species are distinct because these cells secret different mediators; thus each cell represents patentably distinct subject matter.

B. If Group II is elected, applicant is required to elect a method of regulating an inflammation or cellular secretory process (granule release) in a subject comprising administering a composition comprising a MANS peptide or an active fragment thereof, wherein inflammation is bowel diseases, wherein the bowel

disease is a) ulcerative colitis, b) Crohn's disease or c) irritable bowel syndrom. These species are distinct because the pathological conditions differ in etiologies and therapeutic endpoints; thus each condition represents patentably distinct subject matter. Applicant is further required to elect an inflammatory mediator such as a) neutorphils, b) basophils, c) eosinophils, d) monocytes or e) leukocytes. These species are distinct because these cells secret different mediators; thus each cell represents patentably distinct subject matter.

C. If Group III is elected, applicant is required to elect a method of regulating an inflammation or cellular secretory process (granule release) in a subject comprising administering a composition comprising a MANS peptide or an active fragment thereof, wherein inflammation is skin diseases, wherein the skin disease is a) rosacea, b) eczema c) psoriasis or d) severe acne. These species are distinct because the pathological conditions differ in etiologies and therapeutic endpoints; thus each condition represents patentably distinct subject matter. Applicant is further required to elect an inflammatory mediator such as a) neutorphils, b) basophils, c) eosinophils, d) monocytes or e) leukocytes. These species are distinct because these cells secret different mediators; thus each cell represents patentably distinct subject matter.

D. If Group IV is elected, applicant is required to elect a method of regulating an inflammation or cellular secretory process (granule release) in a subject comprising administering a composition comprising a MANS peptide or an active fragment thereof, wherein inflammation is arthritis diseases, and the inflammatory mediator is a) neutorphils, b) basophils, c) eosinophils, d) monocytes or e) leukocytes. These species are distinct because these cells secret different mediators; thus each cell represents patentably distinct subject matter.

E. If Group V is elected, applicant is required to elect a method of regulating an inflammation or cellular secretory process (granule release) in a subject comprising administering a composition comprising a MANS peptide or an active fragment thereof, wherein inflammation is cystic fibrosis diseases, and the inflammatory mediator is a) neutorphils, b) basophils, c) eosinophils, d) monocytes or e) leukocytes. These species are distinct because these cells secret different mediators; thus each cell represents patentably distinct subject matter.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

6. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

7. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maher Haddad whose telephone number is (571) 272-0845. The examiner can normally be reached Monday through Friday from 7:30 am to 4:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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August 20, 2004

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